

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE****RECEIVED  
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Applicant: Jean François Biegun

Serial N°.: 10/534,567

Filed: 11/14/2003

Title: Accessories for removing bone material and method for making same

Examiner: Nicholas Woodall

Attorney Docket N°.: CAC.P0046

**DECLARATION OF Jean François BIEGUN**

I, Jean François Biegun, hereby declares as follows:

I am the inventor in the above identified application, and I am currently the general manager of XNOV a French based company specialized in the manufacture of knee and hip prosthesis as well as of ancillaries and accessories related to such prosthesis, in particular ancillaries and accessories for removing the hip or knee bone in view of the installation of such prosthesis. I have been working in this field for almost 20 years and have been the designated inventor of many US granted patent in the field.

On March 4, 2009, I have made a previous Declaration in which I have stated that:

"I have manufactured a femoral rasp in polycarbonate (Makrolon 2858 from Bayer) and I have had the Shore D Hardness of two samples (one without pre treatment and another one with a pre treatment consisting of exposition to Beta or Gamma rays in view of sterilization) and have found the following results:

For the first sample (no Beta or Gamma rays exposition) the medium value of the Shore D Hardness was found to be 83.3.

For the second sample (pre treated with Beta or Gamma rays exposition) the medium value of the Shore D Hardness was found to be 85.3.

It should be emphasized that the value of the D shore Hardness of the cortical bone ranges between 85 and 95, depending on which part of the bone the shore is being computed and that in the case of the cortical hip or femoral bone which is being rasped in the field of hip or bone prosthesis, it is the less hard part of the bone which is usually being rasped, ie the part of the bone with a D shore Hardness around 85.

It should then be pointed out that with the Beta or Gamma rays exposition pre treatment of the polycarbonate based rasp, it is obtained a value of the hardness which is higher than the one of the bone to be rasped, while without such pretreatment, the hardness stays beyond the hardness of the bone. This explains why prior art polycarbonate based rasp such as described in US 5454815 has never been able to rasp bone, while our new pre treated rasp is indeed able to rasp bone."

In view of the Appeal proceedings with the USPTO for this patent application, I have reviewed my above previous Declaration and I hereby wish to further clarify and supplement it by stating that when I am declaring in my above previous Declaration that "prior art polycarbonate based rasp such as described in US 5454815 has never been able to rasp bone", the term "bone" has to be understood as meaning "hip or knee bone" and not any bone. I believe such interpretation of the term bone is unambiguously derivable from my above previous Declaration taken as a whole and I hereby declare that such interpretation corresponds exactly to what I was intending to declare when I made my previous Declaration.

I further hereby declare that prior art hip rasp such as described in US 5454815 cannot rasp bone having a Shore D Hardness of 85 or more, and since hip bones have a Shore D hardness comprised between 85 and 95, prior art rasp recited in US 5454815 cannot rasp hip bones.

I also declare that all statements made herein of my own knowledge are true and that all statements made herein on information are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Made in Belfort on 21<sup>st</sup> October 2010

Jean François Biegun

